

REMARKS

The Office Action of May 24, 2007 was received and carefully reviewed. Reconsideration and withdrawal of the currently pending rejections are requested for the reasons advanced in detail below.

Claims 1-16 were pending prior to the instant amendment. By this amendment, claim 1 is amended and claims 11-16 are canceled without prejudice or disclaimer. Consequently, claims 1-10 remain pending in the instant application, of which claim 1 is independent.

Claims 1-8 and 11-16 are rejected under 35 U.S.C. §102(a or e) as being anticipated by U.S. Publication No. 2003/0005599 to Panaccione, and claims 9 and 10 are rejected under 35 U.S.C. §102(a or e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Panaccione. These rejections are traversed for at least the reasons advanced in detail below.

Claims 11-16 are canceled herein, rendering this aspect of the rejection moot.

Upon reviewing the cited patent to Panaccione, Applicants contend that Panaccione fails to teach the claimed feature of an *orthotic insert* that is “*heat mouldable to conform to the person's foot* such that to fit said insert to person's foot said insert is heated until it softens sufficiently to permit an upper supporting surface of the insert to conform to said patient's foot to provide the desired biomechanical support and then subsequently cooled, where upon cooling said upper supporting surface of said insert retains the shape to which it has conformed,” (emphasis added), as now recited in amended claim 1. Here, the orthotic insert is produced from *heat mouldable ethyl vinyl acetate*, and thus, is the orthotic insert is *heat mouldable to conform to a person's foot*.

In relation to claims 1 to 10, we emphasize that the claims of the present invention are directed to *an orthotic insert*. An orthotic insert for a shoe provides biomechanical support and correction for a wearer and if it is to function correctly, must be tailored for the particular wearer.

Podiatrists prescribe orthotic inserts. These are specially designed devices that are worn

inside the shoe to control abnormal foot function and/or accommodate painful areas of the foot.

Properly designed foot orthotics may compensate for impaired foot function, by controlling abnormal motion across the joints of the foot. This may result in dramatic improvement in foot symptoms. Typically they are constructed upon a plaster impression of the feet, and modified based on the podiatrist's evaluation of the patient's problem. They are normally quite comfortable, and do not feel hard or uncomfortable in the shoe. Rigid orthotics

normally last for years, additions such as top covers and extensions may require periodic replacement. Some patients, for example the very elderly, however may not tolerate rigid functional orthotics. Under these circumstances, the podiatrist will prescribe an orthotic made from softer materials with special accommodations for painful areas. Orthotics should not be confused with over the counter arch supports or mass produced innersoles. The latter may help the occasional patient with minor arch discomfort, but they frequently fail because they do not properly control foot function and/or do not properly fit the patient's feet.

Accordingly, to further distinguish the invention from the prior art, claim 1 has been amended to further recite "such that to fit said insert to said person's foot said insert is heated until it softens sufficiently to permit an upper supporting surface of the insert to conform to said

patient's foot to provide the desired biomechanical support and then subsequently cooled, where upon cooling said upper supporting surface of said insert retains the shape to which it has conformed."

To enable the Examiner to appreciate the distinction between the prior art and the present invention, we enclose herewith a copy of the advertising literature used by the applicant in marketing its product. Further information can be found on its website; namely www.icbmedical.com.

In direct contrast to Applicants' claimed invention, Panaccione merely teaches the use of an innersole for a shoe without any teaching or suggestion of the innersole being heat mouldable in the manner required by amended claim 1. Accordingly, Panaccione fails to teach or suggest the combination of features recited by at least independent claim 1, as amended, and hence dependent claims 2-10.

With regard to claims 9 and 10, Applicants assert that Panaccione is completely silent with respect to any relationship between deformation resistances, as implied by the Office Action. Accordingly, the Office Action attempts to remedy this deficiency of Panaccione by alleging that the relative “resistance to deformation,” as recited by claims 9 and 10, are somehow “considered either inherent or at least obvious.” Applicants assert that Panaccione neither teaches nor suggests any relative resistance to deformation, as recited by claims 9 and 10.

According to Panaccione, at paragraph [0032], “forefoot piece 10 may be manufactured from laminated layers 12A-12C and 12A’-12C’ of material selected to provide various sizing, cushioning, aeration, and durability properties.” However, Panaccione provides no teaching or suggestion, either implicitly or explicitly, of any relative resistance to deformation of the forefoot piece 10 and the heel piece 20. Moreover, in general, Panaccione is completely silent with regard to relative mechanical properties between the forefoot piece 10 and the heel piece 20. Thus, Applicants assert that Panaccione may not be properly considered to provide any motivation that “[t]he exact % difference in resistance is considered either inherent or at least obvious,” as alleged by the Office Action.

Furthermore, Applicants assert that one of ordinary skill in the art would not have been properly motivated to modify Panaccione to provide for any relative “resistance to deformation,” as recited by claims 9 and 10. Specifically, the relative resistance to deformation may not be properly considered a result-effective variable, but a ratio of deformation resistances of a second portion, which includes a heel region, of an orthotic insert to a first portion (not including the heel region) of the orthotic insert. Here, claims 9 and 10 recite ranges of the second section having --30 to 70 %-- and --40 to 60%-- “more resistant to deformation than said first portion,” respectively. Thus, none of the prior art of record, especially Panaccione, recognizes that different portions/regions of an orthotic insert may function to have different relative resistances to deformation, as recited by claims 9 and 10.

As directed by MPEP 2144.05(II)(B), “[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).” Accordingly, since the prior art of record, or any logical scientific reasoning

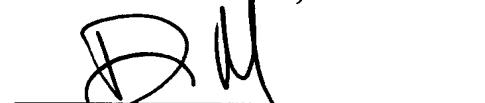
provided by the Office Action, does not recognize that different portions/regions of an orthotic insert may function to have different relative resistances to deformation, as recited by claims 9 and 10, then the parameter recognized, i.e., relative resistance of deformation, was not recognized in the art to be a result-effective variable. Thus, the conclusion that it would have been obvious "to make the materials with the % difference as claimed," is invalid since the parameter of relative resistance to deformation is not recognized as a result-effective variable. Therefore, Applicants assert that the Office Action fails to establish a *prima facie* case of obviousness with regard to at least claims 9 and 10.

As a result, the rejections under 35 U.S.C. §§ 102 (a or e) and 103(a) should be withdrawn since the combination of features recited by at least independent claim 1 is neither taught nor suggested by the cited prior art.

In view of the foregoing, it is respectfully requested that the rejections of record be reconsidered and withdrawn by the Examiner, claims 1-10 be allowed, and the application be passed to issue. If a conference would expedite prosecution of the instant application, the Examiner is hereby invited to telephone the undersigned to arrange such a conference.

Respectfully submitted,

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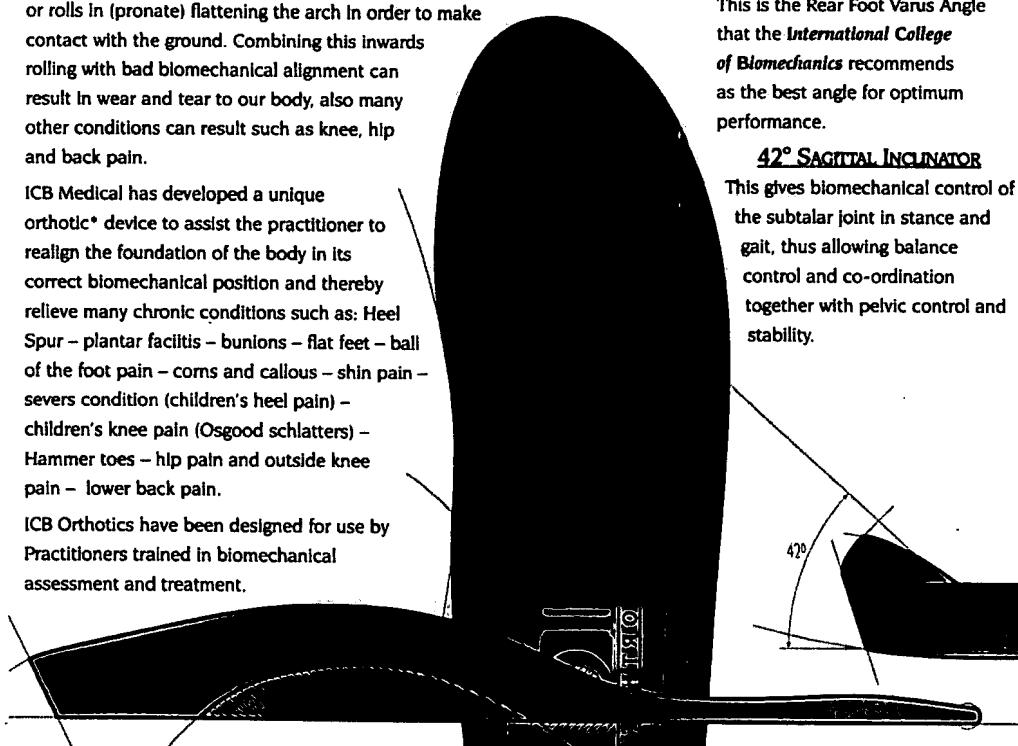
The ICB Orthotic.

Our bodies are called upon to walk predominately on hard unyielding surfaces... for which we were never designed; rather than soft accommodating surfaces, such as grass, sand and soil.

When the surface does not 'give away' the structure of our foot collapses or rolls in (pronate) flattening the arch in order to make contact with the ground. Combining this inwards rolling with bad biomechanical alignment can result in wear and tear to our body, also many other conditions can result such as knee, hip and back pain.

ICB Medical has developed a unique orthotic* device to assist the practitioner to realign the foundation of the body in its correct biomechanical position and thereby relieve many chronic conditions such as: Heel Spur – plantar fascitis – bunions – flat feet – ball of the foot pain – corns and callous – shin pain – severs condition (children's heel pain) – children's knee pain (Osgood schlatters) – Hammer toes – hip pain and outside knee pain – lower back pain.

ICB Orthotics have been designed for use by Practitioners trained in biomechanical assessment and treatment.



ENDORSED BY



HEAT MOLDING

Can be accommodated to foot or cast by applying heat to the orthotic.

5° INTRINSIC REAR FOOT VARUS ANGLE

This is the Rear Foot Varus Angle that the *International College of Biomechanics* recommends as the best angle for optimum performance.

42° SAGITAL INCLINATOR

This gives biomechanical control of the subtalar joint in stance and gait, thus allowing balance control and co-ordination together with pelvic control and stability.

TRIANGULAR SHAFT

This is a mid-foot stabiliser that runs longitudinally from the mid-foot to the forefoot. the shaft splayes out in a triangular fashion, enabling weight to be dispersed across the individual bones of the foot through its unique Weight Distribution System (WDS).

100% EVA

EVA has a long 'construction memory' and can be adjusted to the foot, or to the patient's cast, using applied heat. The unique non-slip surface provides greater foot control in the shoe during the gait and running cycle.

CLOSED CELL CONSTRUCTION

No air bubbles to compress and distort the shape of the orthotic.

WEARING YOUR ORTHOTIC IN

Wear for a period of 1–2 hours per day or until any discomfort occurs. Continue until you are comfortable. Your practitioner can reheat and remould to achieve compliance.

HEAT MOULDING AND FITTING

ICB Orthotics should be heated to achieve maximum patient compliance.

